Mountain-Pacific Quality Health . . . The go-to resource for driving innovation in health care systems

3404 Cooney Drive, Helena, MT 59602
Phone 406.443.6002 • Toll Free Phone 1.800.395.7961
Fax 406.513.1928 • Toll Free Fax 1.800.294.1350

Montana Medicaid Prior Authorization Request Form for Use of Daklinza® (daclatasvir) + Sovaldi® (sofosbuvir)

Daklinza® + Sovaldi® Initial Approval Form

(for Genotype 3)

Note: Forms completed by the providing pharmacy will not be accepted. Forms must be completed by the prescribing office.

Patient's Name:	Patient's Medicaid ID#:
Patient's DOB:	Patient's Gender:
Provider's Name:	Provider's Specialty:
Provider's Phone #:	Provider's Fax #:
Today's Date:	Anticipated Daklinza® + Sovaldi® Start Date:

I. Patient Readiness Evaluation:

Patient psychosocial readiness is a critical component for Hepatitis C treatment success. It is important that any potential impediments to the effectiveness of treatment have been identified and that a plan for dealing with these impediments has been developed. The patient must be educated that abuse of alcohol may cause further liver damage and that abuse of IV injectable drugs will increase the risk of re-infection of Hepatitis C if the virus is cleared. Given the high cost of Hepatitis C treatment, we want to ensure that both the provider and the patient feel that the patient is committed to effectively start and successfully adhere to treatment. We highly recommend that you use a patient readiness evaluation tool such as Prep-C, a free interactive online tool which can be found at the following website: https://prepc.org/. **Please discuss the following questions with your patient, document their responses below, and have patient sign page 2:**

1. **Does patient have a history of alcohol abuse? Yes No**
   - If yes, how long has it been since patient last used alcohol?
   - If yes, is patient attending a support group or receiving counseling? Yes No
2. **Does patient have a history of injectable drug abuse? Yes No**
   - If yes, how long has it been since patient last used an injectable drug?
   - If yes, is patient attending a support group or receiving counseling? Yes No
3. **Does patient have a history of any other controlled-substance abuse? Yes No**
   - If yes, how long has it been since patient last used this substance?
   - If yes, is patient attending a support group or receiving counseling? Yes No
4. **Does patient have difficulties with medication compliance and/or showing up for appointments? Yes No**
   - If yes, how will compliance/ involvement be improved?
5. **Does patient have mental health conditions that are not being adequately treated? Yes No**
   - If yes, please explain, and state the plan for treatment:
6. **Does patient have adequate social support? Yes No**
   - If not, please state a plan to improve support:

MT Medicaid Hepatitis C Patient Readiness Criteria:

1. Patient must not have a history of alcohol abuse, injectable drug abuse, and/or other controlled-substance abuse for at least 6 months prior to starting Hepatitis C treatment. Patient involvement in a support group or counseling is highly encouraged for successful abstinence.

2. Patient must be reasonably compliant with all current medications that are being prescribed for all disease states/conditions to be considered eligible for Hepatitis C treatment.

3. Patient must have a history of showing up for scheduled appointments/labs leading up to the prescribing of Hepatitis C treatment.

4. If patient has mental health conditions, patient must be compliant with mental health medications and/or psychotherapy. If patient has mental health conditions that are not currently being treated, then a mental health consult to assess for patient readiness will be required before Hepatitis C treatment can begin.

Patient signature:_____ **Date:**_____

II. MT Medicaid Daklinza® + Sovaldi® Requirements:

A. What is patient's HCV genotype? (document and attach genotype lab results):

_____

B. Please attach results of testing for HCV Genotype 3 NS5A Y93H polymorphism. If the polymorphism is present, the effectiveness of treatment can be greatly decreased.

_____

C. Documentation of extent of liver damage must be included [liver biopsy fibrosis stage (F0-F4), or any of the following non-invasive test results: APRI score, FibroSure score, or FibroScan results]

_____

Continued… Page 2 of 4

D. Please provide Child-Pugh Classification Score and Grade by evaluating each of 5 measures in table below:

Total points: _____ Child Pugh Grade: _____

	Points Assigned		
PARAMETER	**1**	**2**	**3**
Ascites	Absent	Slight	Moderate
Bilirubin, total (mg/dL)	1.0-2.0	2.0-3.0	>3.0
Albumin (g/dL)	>3.5	2.8-3.5	<2.8
Prothrombin Time			
-Seconds prolonged	1.0-4.0	4.0-6.0	>6.0
-International normalized ratio (INR)	<1.7	1.7-2.3	>2.3
Encephalopathy*	None	Grade 1-2	Grade 3-4

*Encephalopathy is classified as Grade 0 to 4:

Grade

0-no abnormality detected
1-shortened attention span, impaired addition and subtraction skills, mild euphoria or anxiety
2-Lethargy, apathy, disoriented to time, personality change, inappropriate behavior
3-Somnolence, semi-stupor, responsive to stimuli, confused when awake, gross disorientation
4-Coma, little or no response to stimuli, mental state not testable

Child Pugh Grade	Description	Total Points
A	Mild; well-compensated disease	**5-6**
B	Moderate; significant functional compromise	**7-9**
C	Severe; decompensated disease	**10-15**

Adapted from: Pugh RN, Murray-Lyon IM, Dawson JL, Pietroni MC, Williams R. Transection of the oesophagus for bleeding oesophageal varices. Br J Surg. 1973 Aug;60(8):646-9. PMID.

E. List any previously tried Hepatitis C treatments, dates treated, and response:

_____

F. Daklinza® has several drug interactions that may determine the appropriate dose of Daklinza®. Please accurately list all medications patient is currently taking (including OTC medications, vitamins, and herbal/natural products):

_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

G. Patient must meet ALL of the following criteria: (Please check all that apply)

***Any requests not meeting criteria will require review by the MT Medicaid DUR Board.**

- ○ All chart notes related to Hepatitis C evaluation/treatment must be included
- ○ Patient Readiness Evaluation (page 1) must be completed and patient must meet all of the Patient Readiness Criteria listed on page 2
- ○ Documentation of extent of liver damage must be included (see page 2)
  - ○ Individual must have F3 liver fibrosis staging [Must not have cirrhosis (F4 liver fibrosis staging)]
- ○ Patient must have been screened for and must not have the HCV Genotype 3 NS5A Y93H polymorphism
- ○ Must not have decompensated cirrhosis
- ○ Diagnosis of chronic hepatitis C infection with HCV genotype 3
- ○ Patient is 18 years of age or older
- ○ Must be prescribed by a gastroenterologist, infectious disease specialist, or a hepatologist who provides initial consultation and continues to monitor patient throughout course of treatment
- ○ Daklinza® must be taken in combination with Sovaldi®
- ○ Patient does not have severe renal impairment (CrCl <30 ml/min) or end stage renal disease requiring dialysis.
- ○ Patient must not be taking any of the following medications (please circle if patient is taking): amiodarone, carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifabutin, rifampin, rifapentine, St. John's wort, or tipranavir/ritonavir
- ○ Patient must not have had previous treatment with telaprevir, boceprevir, simeprevir, sofosbuvir, ledipisvir, ombitasvir, paritaprevir, ritonavir, dasabuvir, or daclatasvir
- ○ Patient must not have had treatment with any other Hepatitis C medications within the last 6 months

H. Requested Treatment Regimen: (Check the regimen that applies)*

- ○ **HCV Genotype 3:** Daklinza®* 60 mg + Sovaldi® 400 mg once daily for 12 weeks
- ○ **HCV Genotype 3 (with strong CYP3A inhibitor drug interaction):** Daklinza®** 30 mg + Sovaldi® 400 mg once daily for 12 weeks
- ○ **HCV Genotype 3 (with moderate CYP3A inducer drug interaction):** Daklinza®** 90 mg (60 mg + 30 mg) + Sovaldi® 400 mg once daily for 12 weeks

***Preferred treatment may be subject to the MT Medicaid preferred Drug List.**

****Note: Standard dose of Daklinza® is 60 mg, but it may have to be decreased to 30 mg or increased to 90 mg (60 mg + 30 mg), depending on drug interactions.**

Limitations:

1. Quantity Limit of **28 tablets per 28 days** of each: **Daklinza®** [30 mg, 60 mg, or 90 mg (30mg + 60 mg)] and **Sovaldi®** (400 mg)
2. **Initial approval** will be granted for **4 weeks**.
3. Continuation of therapy beyond 4 weeks will require completion of **Daklinza® + Sovaldi® Renewal Form**.

Provider's Signature:_____**Date:**_____

Please complete form, attach documentation, and fax to:
Medicaid Drug Prior Authorization Unit at 1-800-294-1350

Mountain-Pacific Quality Health . . . The go-to resource for driving innovation in health care systems

3404 Cooney Drive, Helena, MT 59602
Phone 406.443.6002 • Toll Free Phone 1.800.395.7961
Fax 406.513.1928 • Toll Free Fax 1.800.294.1350

Montana Medicaid Prior Authorization Request Form for Use of Daklinza® (daclatasvir) + Sovaldi® (sofosbuvir)

Daklinza® + Sovaldi® Renewal Form

Note: Forms completed by the providing pharmacy will not be accepted. Forms must be completed by the prescribing office.

Patient's Name:	Patient's Medicaid ID#:
Patient's DOB:	Patient's Gender:
Provider's Name:	Provider's Specialty:
Provider's Phone #:	Provider's Fax #:
Date:	

Date Daklinza® + Sovaldi® were started:_____

Treatment Regimen: (check one)

- **HCV Genotype 3:** Daklinza®* 60 mg + Sovaldi® 400 mg once daily x 12 weeks
- **HCV Genotype 3 (with strong CYP3A inhibitor drug interaction):** Daklinza®* 30 mg + Sovaldi® 400 mg once daily x 12 weeks
- **HCV Genotype 3 (with moderate CYP3A inducer drug interaction):** Daklinza®* 90 mg (60 mg + 30 mg) + Sovaldi® 400 mg once daily x 12 weeks

Note: Standard dose of Daklinza® is 60 mg, but dose may have been decreased to 30 mg or increased to 90 mg (60 mg + 30 mg), depending on drug interactions.

Renewal Requirements: The following requirements must be met. (Check all that apply)

- Patient must have been **compliant** with Daklinza® and Sovaldi® as per protocol
- Patient must still be taking Daklinza® in combination with Sovaldi®

Renewal Limitations:

1. Quantity Limit of **28 tablets per 28 days** of each: Daklinza® [30 mg, 60 mg, or 90 mg (30mg + 60 mg)] and Sovaldi® (400 mg)
2. If patient meets criteria, Daklinza® + Sovaldi® will be authorized in **4 week increments** (for a maximum total of **12 weeks**)

Note: Daklinza® + Sovaldi® Renewal Form will need to be submitted for each 4 week authorization.

Provider's Signature:_____Date:_____

Please complete form, attach documentation, and fax to:
Medicaid Drug Prior Authorization Unit at 1-800-294-1350